UNIVERSAL HIV TESTING OF PREGNANT WOMEN

DESCRIPTION

Universal HIV Testing of Pregnant Women is a service to identify women who are HIV infected during pregnancy. CBOs should consider providing referral services to medical providers who serve women to ensure that the HIV prevention and service needs of both HIV-infected and HIV-negative women at high risk and their children are met. CBOs who choose to partner with medical providers should document this relationship and delineate the roles and responsibilities of each partner in a memorandum of understanding.

Background

Since the first pediatric case of HIV infection was documented in 1984, tremendous medical and public health achievements have been made in preventing mother-to-child transmission of HIV. A key step toward ensuring that the perinatal HIV interventions offered are effective is making sure that care providers know the HIV status of the pregnant women in their care.

CDC is revising its HIV counseling and testing guidelines. Separate guidelines are being developed for HIV testing in health care settings and HIV counseling, testing, and referral in non-healthcare settings. The guidance provided in this document may change, depending on the results of the guideline revision process; however, until that time, the recommendations in this document should be adhered to.

Specifically, Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings will be published later in 2006. They will replace CDC's 1993 Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute-Care Hospital Settings; and they will update aspects of CDC's 2001 Revised Guidelines for HIV Counseling, Testing, and Referral that apply to health care settings and the 2001 Revised Recommendations for HIV Screening of Pregnant Women. In addition, the process for updating recommendations for HIV testing in non-healthcare settings is under way, with publication expected in 2007.

Goal

The goal is reducing mother-to-child HIV transmission in the United States. This goal can be met by identifying pregnant women for whom antiretroviral and obstetric interventions can reduce the newborn's risk for HIV infection.

How It Works

Maximal reduction of perinatal HIV transmission in the United States depends on ensuring that

- pregnant women receive prenatal care
- all pregnant women are routinely screened for HIV
- recommended antiretroviral regimens are used during pregnancy, labor, delivery, and after birth for HIV-infected women and their newborns, and obstetrical interventions are provided during labor and delivery when indicated
- routine HIV screening during labor and delivery, or to the newborn after birth, is available to women whose HIV status has not been previously determined[1]

Opt-in Approach
Pregnant women are given pretest counseling and must specifically consent, usually in writing, to an HIV test.

Opt-out Approach (recommended by CDC)
Pregnant women are notified that an HIV test will be included in the standard battery of prenatal tests and procedures and that they may decline testing.

Research Findings
When a woman is identified as being HIV-infected during pregnancy, antiretroviral and obstetrical interventions can reduce her risk for transmitting HIV to her child to 2% or less. When preventive antiretroviral treatment is not initiated until labor or birth, the risk for transmission is 9% to 13%.[2–4] In the United States, without any intervention, the risk for transmission is approximately 25%.[5]

Opt-in Approach
Among states in which the opt-in approach was used and in which data were collected from medical records during 1998–1999, testing rates ranged from 25% to 69%. Population-based data from Canada showed testing rates in 3 provinces using the opt-in approach to be 54% to 83%.

Opt-out Approach
In contrast, medical record data from Tennessee, which uses the opt-out approach, revealed a testing rate of 85%. Data from Canadian provinces using opt-out approaches showed a 98% testing rate in Alberta and a 94% testing rate in Newfoundland and Labrador. At the University of Alabama's 8 prenatal clinics, HIV testing rates rose from 75% to 88% after the opt-out approach was implemented.[6]

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements
Core elements are those parts of an intervention that must be done and cannot be changed. **Core elements are essential and cannot be ignored, added to, or changed.**

Universal HIV Testing of Pregnant Women has the following 6 core elements:

- Routinely offer universal prenatal HIV testing.

- Routinely offer rapid HIV testing during labor for women whose HIV status is still unknown.
- Offer rapid HIV testing postpartum for women of unknown HIV status or for their newborns when rapid testing at labor and delivery is not possible or has been previously refused. (Some states mandate screening of newborns in these circumstances.)
- Perform confirmatory testing for all preliminary positive rapid HIV test results.
- When using the rapid HIV test, follow all standards and procedures related to the use of the rapid test, including guidelines for providing preliminary results and obtaining specimens for confirmatory testing (see Procedural Guidance for Rapid HIV Testing in Nonclinical Settings in this document for additional information on the rapid HIV test).
- For pregnant women with positive HIV test results, facilitate access to appropriate obstetric, medical, and social services for prevention, care, and treatment and follow-up for their newborns.

Key Characteristics

Key characteristics are those parts of an intervention (activities and delivery methods) that can be adapted to meet the needs of the CBO or target population.

Universal HIV Testing of Pregnant Women has the following key characteristics:

- Develop an information sheet with all relevant information regarding HIV prevention counseling, testing, and referral services; distribute this sheet at gynecologic appointments or during labor.
- Offer testing on an opt-out basis.
- During the third trimester of pregnancy or during labor, rescreen all women who are seen in health care facilities in which HIV prevalence is high (> 0.5% prevalence among women of childbearing age) or who are seen in facilities in which prevalence is low but the women are at high risk for HIV infection.
- Establish a system to document test results and to track specimens sent for confirmatory testing.
- Develop a system to document and track refusal of HIV testing.
- Partner with care providers to provide information about the expected public health benefits of the opt-out approach to local representatives of national health care provider organizations, community groups that focus on maternal and child health issues, and state and local government officials.

Procedures

Procedures are detailed descriptions of some of the above-listed elements and characteristics.

Procedures for Universal HIV Testing of Pregnant Women are as follows:

Promoting Testing

CBOs should initiate discussions with care providers serving pregnant women about

- the benefits of routine testing for HIV
- the benefits of partnering to address routine testing of their patients
- the ability of the CBO to provide client-centered posttest counseling without disrupting the flow of the clinic
- ready access to services and referrals for women whose HIV test results are positive

Training

CBOs should work with the state or local health department and the AIDS Education and Training Centers of the Health Resources and Services Administration to facilitate the training of providers who choose to partner with the CBO. Training should ensure use of the opt-out approach, including documenting in a woman's medical chart her HIV test results or that she has declined testing.

Providing Information

In collaboration with medical providers, CBOs should design an information sheet to be given to all untested pregnant women during their medical appointments. Informational videos may also be used. The information should

- describe risk factors for transmitting or acquiring HIV
- describe features of the HIV antibody test and possible results
- describe the benefits to mother and child of knowing about and treating HIV
- list HIV prevention, support, and care services available within the community
- advise the women that HIV testing is provided as a routine part of prenatal care and that they have the right to decline the test

Testing During Prenatal Care

The HIV antibody test may be included in a standard battery of laboratory tests used. Although informed consent is required for HIV testing, if the provider has informed a woman that the HIV test is included in the standard battery and that she can decline testing, consent for the battery of tests may be sufficient; however, CBOs should be aware of their relevant state laws. HIV test results or the refusal to be tested should be documented in the woman's medical chart. Fact sheets on HIV testing for providers, an information sheet on HIV and other prenatal tests for women, and forms for documenting HIV test results or refusal have been developed by the American College of Obstetricians and Gynecologists and are available on their Web site.

Retesting

For women at health care facilities in which HIV prevalence is high (> 0.5% prevalence among women of childbearing age) or who are in facilities in which prevalence is low but the women are at high risk for HIV infection (e.g., women with HIV-infected partners), testing should be offered a second time if the test was initially declined or if the initial results were negative.

Testing at Labor and Delivery

If the woman's HIV status is unknown at the time of labor and delivery, rapid HIV testing should be offered. Working with key partners, CDC has developed a model

protocol for implementing rapid HIV testing in labor and delivery settings. Again, the woman should be informed, as described above under Providing Information.

If the mother's HIV status remains unknown after delivery, rapid HIV testing should be offered for the mother or the newborn as soon as possible. Some states mandate screening of the newborn in this circumstance. CBOs should be aware of their individual state laws.

Preventing Transmission
A woman who receives a positive HIV test result at any time during pregnancy or labor and delivery should be informed that medications can be given to her and to her child to reduce the chance that the child will become HIV infected. For some women, a scheduled cesarean section at 38 weeks gestation may be indicated. A woman whose rapid test results during labor and delivery are preliminary positive should immediately be offered medication for her and her child to reduce the chance that the child will become HIV infected. Preliminary positive results should be confirmed with a Western blot or immunofluorescence antibody test.

RESOURCE REQUIREMENTS

People
Universal HIV Testing of Pregnant Women needs paid or volunteer staff members who are trained in providing information about HIV testing and referral. If rapid HIV testing will be used, involved staff members must be trained in the delivery of rapid HIV testing. The number of staff needed depends on the number of tests needed and the type of test used. The number of tests completed per hour depends on the needs of the clients, the abilities of the counselor, and the type of test used (rapid or conventional).

Space
Universal HIV Testing of Pregnant Women can be done anywhere that confidentiality of clients can be assured (e.g., private area or room) and where a specimen can be collected according to minimal standards as outlined by the Occupational Safety and Health Administration. Additionally, for rapid testing, the setting must have a flat surface, acceptable lighting, and ability to maintain temperature ability in the range recommended by the test manufacturer for performing the test.

RECRUITMENT

CBOs implementing Universal HIV Testing of Pregnant Women should encourage medical providers at the partner clinics to promote HIV testing during prenatal care visits, during labor and delivery, or during the postpartum period. Information sheets or videos used during the prenatal visits can facilitate discussions about HIV risk and testing and

can remind the provider to offer testing or refer women for counseling, testing, and referral.

POLICIES AND STANDARDS

Before a CBO attempts to implement Universal HIV Testing of Pregnant Women, the following policies and standards should be in place:

Confidentiality

A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from the client or her legal guardian must be obtained.

Cultural Competence

CBOs must strive to offer culturally competent services by being aware of the demographic, cultural, and epidemiologic profile of their communities. CBOs should hire, promote, and train all staff to be representative of and sensitive to these different cultures. In addition, they should offer materials and services in the preferred language of clients, if possible, or make translation available, if appropriate. CBOs should facilitate community and client involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care,* which should be used as a guide for ensuring cultural competence in programs and services. Please see Ensuring Cultural Competence in the Introduction of this document for standards for developing culturally and linguistically competent programs and services.

Data Security

To ensure data security and client confidentiality, data must be collected and reported according to CDC requirements.

Informed Consent

Women should be told that HIV testing will be included in the standard battery of prenatal tests and procedures and that they have the right to decline testing. This information may be included in a consent form that women sign for all prenatal care and services. Specific procedures regarding consent will depend on state and local laws, regulations, and policies. Refusal to be tested should be documented in the medical chart.

Legal and Ethical Policies

Universal HIV Testing of Pregnant Women requires specialized training and deals with private medical information. CBOs must know their state laws regarding who may offer HIV testing to clients, conduct rapid HIV testing, and provide results and referrals. Knowledge of the laws regarding disclosure of a client's HIV status (whether positive or negative) to sex partners and other third parties is also important. Additionally, some

state laws prohibit the disclosure of preliminary positive test results. CBOs must also know, and adhere to all Clinical Laboratory Improvement Amendments regulations for testing, documentation, and use of logs relating to test implementation. Some states require that newborns be screened for HIV if the mother's HIV status is unknown. CBOs and their medical provider partners should be familiar with state laws regarding this requirement. Finally, CBOs must inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.

Referrals

CBOs must be prepared to refer clients as needed. In addition, CBOs must provide necessary referrals for newborns exposed to HIV. For clients who need additional assistance in decreasing risk behavior, providers must know about and have linkage relationships with referral sources for HIV and ongoing gynecologic care as well as prevention interventions and counseling, such as partner counseling and referral services and health department and CBO prevention programs for persons living with HIV.

Safety

HIV testing services may pose potentially unsafe situations (e.g., the risk of transmitting bloodborne pathogens). CBOs should develop and maintain written detailed guidelines for ensuring minimal safety standards with regard to specimen collection as outlined by the Occupational Safety and Health Administration and for safeguarding the security of the data collected, client confidentiality, and the chain of custody for testing supplies and collected client specimens.

Volunteers

If the CBO uses volunteers to assist with or conduct testing and referral services, then the CBO should know and disclose how their liability insurance and worker's compensation applies to volunteers. CBOs must ensure that volunteers also receive the same training and are held to the same performance standards as employees. All training should be documented. CBOs must also ensure that volunteers sign and adhere to a confidentiality statement.

QUALITY ASSURANCE

The following quality assurance activities should be in place when implementing Universal HIV Testing of Pregnant Women:

Counselors

Training

CBOs should have a training program in place for all new employees, existing employees, and volunteers that will be providing counseling, testing, and referral services. This program should ensure that all providers of counseling, testing, and referral receive

- adequate training
- annual training updates

- continuing education
- adequate supervision to implement counseling, testing, and referral services and the rapid HIV test, if appropriate

The program should also ensure that counseling, testing, and referral providers are skilled and competent in the provision of services (by using observed practice of counseling, testing, and referral sessions with feedback to counselors and of rapid HIV test procedures, if needed).

Protocol Review
CBOs should have in place a review mechanism to ensure that all testing protocols are followed as written. Quality assurance activities can include observation as well as role-playing demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should help counselors develop skills for delivering the intervention. Selected intervention record reviews should focus on assuring that consent was obtained or documented for all clients and all process and outcome measures are completed as required. For CBOs using rapid HIV test technology, control kits (available from the test kit manufacturer) should be used to ensure reliability and validity of the test process and materials. (For quality assurance activities related to rapid HIV testing, please review the Procedural Guidance for Rapid HIV Testing in Nonclinical Settings in this document.)

Clients
Women's satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number referrals made, the number of referrals completed, and response to the service.

Setting
Supervisors should periodically review the testing facility to ensure that a private and confidential setting is available for testing and that the waiting time for a test at this setting does not create a barrier to testing. Feedback should be solicited from medical providers to ensure that test providers are integrated appropriately into the clinic setting.

MONITORING AND EVALUATION

At this time, specific guidance on the collection and reporting of program information, client-level data, and the program performance indicators is under review and will be distributed to agencies after notification of award.

General monitoring and evaluation reporting requirements for the programs listed in the Procedural Guidance will include the collection of standardized process and outcome measures as described in the Program Evaluation and Monitoring System (PEMS). PEMS is a national data reporting system that includes a standardized set of HIV prevention data

variables, web-based software for data entry and management, data collection and evaluation guidance and training, and software implementation support services.

Funded agencies will be required to enter, manage, and submit data to CDC using PEMS. Furthermore, agencies may be requested to collaborate with CDC in the implementation of special studies aimed at assessing the effect of HIV prevention activities on at-risk populations.

KEY ARTICLES AND RESOURCES

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